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Carol E Rozek
Novo Nordisk of North America Inc
Suite 6400
405 Lexington Avenue
New York, NY 10174-6401

EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/671,461

Applicant(s)

STABY, ARNE

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4,6 and 11-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2,4,6 and 11-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/522,694.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- ☐ Interview Summary (PTO-413) Paper No(s) ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 2, 4, 6 and 11-14 are pending.

Applicants' preliminary amendment filed on September 27, 2000 (Paper No. 2) is acknowledged. In the cross reference to related applications, applicants cite the parent application, 09/522,694 without reflecting its current status. Please update the status of 09/522,694. Claims 1, 3, 5 and 7-10 have been cancelled, and new claims 11-14 have been added. Thus, claims 2, 4, 6 and 11-14 are examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 6, 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 6 is indefinite because of the use of the term "and/or" or "if necessary". The term "and/or" or "if necessary" renders the claim indefinite, it is unclear whether the limitation after "and/or" is included or not, and if included is to be read as an alternative "or" or the conjunctive "and", and it is also unclear when the limitations following the term "if necessary" are part of the claimed invention. What are the criteria for determining the "if necessary"?
4. Claims 11 and 12 are indefinite because of the use of the term "derivatives thereof", "vira" or "FFR-Factor VIIa". The term "derivatives thereof", "vira" or "FFR-

Factor VIIa” renders the claim indefinite, it is not clear what compound the derivative is, and how different the derivative is from the parent compound, what vira is, and what “FFR” stands for, if it is referred to a peptide, three-letter code should be used.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 2, 6, 11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Lile *et al.* (U. S. Patent 5,606,031).

Lile *et al.* teach recombinant sulfonlated neurotrophic factor (NGF) is purified by anion exchange chromatography, the sulfonlated NGF mixture was diluted in Buffer A (8 M urea, 20 mM Tris-HCl, pH 9.0), and the solution was applied to Pharmacia Q-Sepharose column and washed with Buffer A to remove the impurities. The sulfonlated NGF was then eluted by lowering the pH using Buffer B (8 M urea, 36 mM MES, pH 6.0), or eluted with a linear gradient from Buffer A to Buffer B in 10 column volumes (column 12, lines 52-67; Example 2; claim 2, 6, 11, 14). The reference also teaches NGF monomer contains 6 cysteines, thus the fully sulfonlated monomeric form of NGF contains additional six negative charges, which lowers the effective isoelectric pH and allows the use of anion exchange chromatography at lower pH, and 8 M urea is used for solubilizing the protein (column 9, lines 12-22), which corresponds to the ratio of 1:1.1 of urea to water (claim 13).

6. Claims 2, 6 and 11-14 are rejected under 35 U.S.C. 102(b) as anticipated by Jorgensen *et al.* (US Patent 3,907,676).

Jorgensen *et al.* teach insulin is purified from a mixture containing antigenic insulin-like substances by an anion exchange column which is eluted with monohydric aliphatic alcohol-containing buffer solution, where the eluent has the same pH as the solution containing the mixture with the same ionic strength, or continuous or stepwise increase of the ionic strength during the elution (columns 2-4, Examples; Fig. 1; claims 2, 6, 11, 12 and 14). The antigenic insulin-like substances which are eluted first from anion exchange column (Fig. 1) are those having less affinity to the positively charged resin than insulin because these substances have less negative charges as compared to insulin. The monohydric aliphatic alcohol such as ethanol is used in a concentration of 40-80% (v/v) which corresponds to the ratio of 1:1.9 (w/w, claim 13) to 1:0.3 of ethanol to water.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2, 4, 6, 11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lile *et al.* (U. S. Patent 5,606,031) in view of Binz *et al.* (U. S. Patent 6,113,911, 102(e) date, October 4, 1996).

Lile *et al.* teach recombinant sulfonlated neurotrophic factor (NGF) is purified by anion exchange chromatography, the sulfonlated NGF mixture was diluted in Buffer A (8 M urea, 20 mM Tris-HCl, pH 9.0), and the solution was applied to Pharmacia Q-

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Sepharose column and washed with Buffer A to remove the impurities. The sulfonlated NGF was then eluted by lowering the pH using Buffer B (8 M urea, 36 mM MES, pH 6.0), or eluted with a linear gradient from Buffer A to Buffer B in 10 column volumes (column 12, lines 52-67; Example 2; claim 2, 6, 11, 14). The reference also teaches NGF monomer contains 6 cysteines, thus the fully sulfonlated monomeric form of NGF contains additional six negative charges, which lowers the effective isoelectric pH and allows the use of anion exchange chromatography at lower pH, and 8 M urea is used for solubilizing the protein (column 9, lines 12-22), which corresponds to the ratio of 1:1.1 of urea to water (claim 13). However, Lile *et al.* do not disclose applying the same procedure for industrial use. Binz *et al.* disclose an immunogenic agent containing a peptide can be purified on an anion exchange column under industrial condition. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to apply the method of purifying a peptide as indicated by Lile *et al.* for industrial use as suggested by Binz *et al.* (claim 4) because the suggestion of using isocratic conditions is advantageous under industrial conditions for purifying a peptide (column 5, lines 5-14). Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

February 6, 2003



CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600